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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,342	01/26/2001	Mark G. Fleischhacker	058442/9191	6291

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MICHAEL BEST & FRIEDRICH, LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON, WI 53701

[REDACTED] EXAMINER

MARMOR II, CHARLES ALAN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

3736

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	MF
	09/770,342	FLEISCHHACKER, MARK G.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 December 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed December 2, 2002. The Examiner acknowledges the amendments to the Specification; the amendments to claims 4, 5, 14, 15, 18 and 19; and the cancellation of claims 22-24. Claims 1-21 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-12, 16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Cordis Corporation. Cordis Corporation teaches a guide wire including a core wire comprising a non-metallic, non-woven material. The core wire may be tapered such that the diameter of a distal section is smaller and more flexible than medial and proximal sections of the core wire. The diameters of the distal, medial and proximal sections of the core wire may otherwise be substantially the same. A hydrophilic, polymeric coating covers the length of the core wire (claim 17). The core wire is constructed of a polymeric material and is covered with a second polymeric material. The core wire may also comprise reinforcing carbon fibers (claim 11).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cordis Corporation in view of Sirhan et al. Cordis Corporation teaches all of the limitations of the claims except that the core wire comprises polyetheretherketone. Sirhan et al. teach that polyetheretherketone is known to be a conventional polymeric material that is suitable for constructing guidewires and catheters (col. 9, lines 46-53). It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use polyetheretherketone to make a core wire similar to that of Cordis Corporation in view of the teachings of Sirhan et al. as a design choice, merely selecting a conventional polymeric material that is known to be suitable for the construction guidewires and catheters.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cordis Corporation in view of Nobuhiko. Cordis Corporation teach all of the limitations of the claim except that the core wire is coated with PEBA^X polyethermide. Nobuhiko teaches coating a guidewire core **1** with PEBA^X polyethermide **2** to provide the guidewire with prolonged lubricating ability. It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use PEBA^X polyethermide to coat a core wire similar to that

of Cordis Corporation in view of the teachings of Nobuhiko in order to provide the guidewire with prolonged lubricating ability.

7. Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cordis Corporation in view of Sirhan et al., and further in view of Moutafis et al.

Cordis Corporation teaches a guidewire having a core wire formed of polymeric materials that is substantially completely covered with a second polymeric material **18**. Page 7, lines 22-24, list some possible polymeric materials which can be used to form the core wire. Page 6, lines 19-20, list some possible polymeric materials which can be used to construct the covering **18**. Cordis Corporation teach all of the limitations of the claims except that polyetheretherketone and polyetherimide are used as the polymeric materials for construction.

Sirhan et al. teach that polyetheretherketone is known as a conventional polymeric material that is suitable for constructing guidewires and catheters (col. 9, lines 46-53). It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use a polyetheretherketone to make a core wire similar to that of Cordis Corporation in view of the teachings of Sirhan et al. as a design choice, merely selecting a conventional polymeric material that is known to be suitable for the construction guidewires and catheters.

Cordis Corporation, as modified by Sirhan et al., teach all of the limitations of the claims except that the core wire is coated with polyetherimide. Moutafis et al. teach a plastic coated medical guidewire where a core wire is coated by a polyetherimide sleeve **14** (col. 3, lines 61-65) which is further coated with a hydrophilic lubricous coating **20** (col. 4, line 33). It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to

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coat a polyetheretherketone a core wire similar to that of Cordis Corporation as modified by Sirhan et al., with a polyetherimide jacket and a lubricous coating in view of the teachings of Moutafis et al. as a design choice, merely selecting conventional polymeric materials to construct a guidewire that are known to provide a guidewire with steerability, flexibility, resistance to kinking and stiffness, and lubricity.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solar et al. in view of Zoeller. Solar et al. teach a guidewire and a method for manufacture thereof having a core wire formed of a carbon-fiber composite (paragraph [0044]). Solar et al. does not disclose expressly that the fibers are randomly disposed and bound by a resin. Zoeller teaches that carbon fiber is a composite material including a plurality of fibers bound together by a resin. It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made that the composite carbon fiber of the core wire of Solar et al. would inherently include a resin binder in light of the teachings of Zoeller. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a carbon fiber composite including randomly disposed fibers because Applicant has not disclosed that the use of randomly disposed polymer fibers provides an advantage, is used for a particular purpose, or solves a stated problem. Therefore, it would have been an obvious matter of design choice to use a carbon fiber composite having randomly disposed fibers to form the core wire of Solar et al. as modified by Zoeller to obtain the invention as specified in claim 19.

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9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solar et al. in view of Zoeller as applied to claim 19 above, and further in view of Heilman et al. Solar et al. and Zoeller teach all of the limitations of the claim except that a coil wire is disposed about a distal segment of the core wire. Heilman et al. teach a guide wire having a coil wire disposed about a core wire to provide a guidewire that is flexible yet strong enough to resist kinking while doing no damage to the vascular system of a patient. It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to place coil wire similar to that of Heilman et al. about a distal segment of a core wire similar to that of Solar et al., as modified by Zoeller, in order to provide a guidewire that is flexible yet strong enough to resist kinking while doing no damage to the vascular system of a patient.

10. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solar et al. in view of Zoeller as applied to claim 19 above, and further in view of Sato et al. Solar et al. and Zoeller teach all of the limitations of the claim except that the binder resin is vinyl ester. Sato et al. teach that it is advantageous to use vinyl ester as a binder resin in a carbon fiber composite because of its corrosion resistance and wokability. It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use vinyl ester as a binder resin in a carbon fiber composite similar to that of similar to that of Solar et al., as modified by Zoeller, in view of the teachings of Sato et al. as a design choice, merely selecting a binder resin known to have excellent corrosion resistance and workability properties.

Response to Arguments

11. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

Applicant contends that the Cordis Reference is not prior art under 35 USC 102(a); that the Osborne reference teaches core fibers that are longitudinally oriented and does not anticipate the randomly disposed fibers recited in claims 19-21 of the instant application; that the Sicurelli reference is non-analogous art; that the Munsinger reference does not suggest that PEEK would be a useful material for core wires of guidewires; and that the Palermo reference teaches a proximal portion of a guidewire formed of PEBAK, thus teaching away from the PEBAK covering of the instant invention. These arguments are moot in view of the new grounds of rejection set forth hereinabove.

While not being a valid prior art reference under 35 USC 102(a), the Cordis Corporation reference is valid prior art under 35 USC 102(e)(1). A WIPO publication of an international application (PCT) is valid prior art under 102(e)(1) if the application was filed on/after Nov. 29, 2000; published in English; and designates the US. Since the U.S. Provisional Application of which the Cordis Corporation reference makes a claim for priority supports the disclosure of WIPO publication, the § 102(e)(1) date for the WIPO publication is June 12, 2000.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9323 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II
Examiner
Art Unit 3736

CAM
February 27, 2003